



FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV336720002
Express Mail Label Number

August 16, 2004
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF
BURKHARD SCHLÜTERMANN

Art Unit: 1615
Examiner: JAMES M.
SPEAR

INTERNATIONAL APPLICATION NO: PCT/EP98/00794
FILED: 12 FEBRUARY 1998
U.S. APPLICATION NO: 09/367,361
35 USC §371 DATE: 11 AUGUST 1999
FOR: OXACARBAZEPINE FILM-COATED TABLETS

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 of the international application. Therefore, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

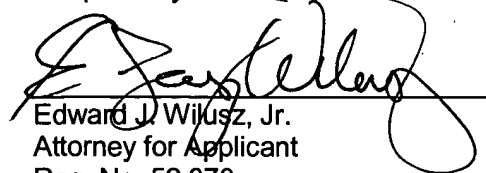
In accordance with 37 C.F.R. §1.56, applicant wishes to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Copies of the asterisked references cited which are U.S. patent and U.S. Patent application publications pursuant to the waiver of requirement under 37 CFR 1.98(a)(2)(i) issued in the Official Gazette dated August 5, 2003, are not provided. Copies of the remaining non-asterisked references are enclosed.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080
(862) 778-7960

Respectfully submitted,


Edward J. Wilusz, Jr.
Attorney for Applicant
Reg. No. 52,370

Date: *16-Aug-2004*

ATTY. DOCKET NO.

4-21233A

APPLICATION NO.

09/367,361

APPLICANT

Burkhard Schlütermann

FILING DATE

AUGUST 11, 1999

Group

1615

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	* 4,945,149	7/31/90	Matsumoto et al.			
	AB	* 4,897,270	1/30/90	Deutsch et al.			
	AC	* 5,840,335	11/24/98	Wenzel et al. (English Equivalent to DE 3932987)			
	AD	* 4,857,336	8/15/89	Khanna et al.			
	AE	* 5,231,089	7/27/93	Bodor			
	AF	* 5,476,654	12/19/95	Conte et al.			
	AG	* 4,452,738	6/5/84	Aufderhaar			
	AH						
	AI						
	AJ						
	AK						
	AL						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AM	835,956	5/25/60	GB			<input type="checkbox"/>	<input type="checkbox"/>
	AN	907,309	10/3/62	GB			<input type="checkbox"/>	<input type="checkbox"/>
	AO	2 195 248	4/7/88	GB			<input type="checkbox"/>	<input type="checkbox"/>
	AP	WO 01/32183	5/10/01	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AQ	EP 0 435 826	12/18/90	EPO			<input type="checkbox"/>	<input type="checkbox"/>

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	Austria-Codex Fachinformation 1995/96 (for Trileptal)
	AS	Appel L. E. et al., "Formulation and Optimization of a Modified Microporous Cellulose Acetate Latex Coating for Osmotic Pumps," Pharmaceutical Research, Vol. 9, No. 12, pp. 1664-1667 (1992)
	AT	Bodmeier R. et al., "Constant Potassium Chloride Release from Microporous Membrane-Coated Tablets Prepared with Aqueous Colloidal Polymer Dispersions," Pharmaceutical Research, Vol. 8, No. 3 (1991)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO.

4-21233A

APPLICATION NO.

09/367,361

APPLICANT

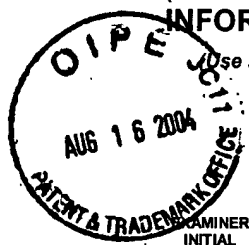
Burkhard Schlütermann

FILING DATE

AUGUST 11, 1999

Group

1615



OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

DA	CA129:180164, Schlutermann, WO9835681, abstract
DB	Degen, P.H. et al., "The Influence of Food on the Disposition of the Antiepileptic Oxcarbazepine and its Major Metabolites in Healthy Volunteers," Biopharmaceutics & Drug Disposition, Vol. 15(6), pp. 519-526, (1994)
DC	Fassihi A.R. et al., "Dissolution of Theophylline from Film-coated Slow Release Mini-tablets in Various Dissolution Media," J. Pharm. Pharmacol., Vol. 41, pp. 369-372 (1989)
DD	Heli Jung et al., "Influence of food on bioavailability of carbazepine," Pharmaceutical Research, Vol. 11(10) Supl., p. s219 (1994)
DE	Lindholm T. et al., "Polysorbate 20 as a drug release regulator in ethyl cellulose film coatings," J. Pharm. Pharmacol. Vol. 38, pp. 686-688 (1986)
DF	McLean M.J., "Oxcarbazepine: Mechanisms of Action," Epilepsia, Vol. 35, S5-S9 (1994)
DG	Parikh N.H. et al., "Aqueous Ethylcellulose Dispersion of Ethylcellulose. I. Evaluation of Coating Process Variables," Pharmaceutical Research, Vol. 10, No.4, pp. 525-534 (1993)
DH	Porter S.C. et al., "The permeability of enteric coatings and the dissolution rates of coated tablets," J. Pharm. Pharmacol., Vol. 34, pp. 5-8 (1982)
DI	Schwabe S., "Clinical Development Outlook of Oxcarbazepine," Epilepsia, Vol. 35, S2-S4 (1994)
DJ	Notice of Opposition against European Patent No. EP 0 966 287 B1 (European Application No. 98908091.6) entitled "Oxcarbazepine Film-Coated Tablets" in the name of and on behalf of Technimede Sociadada, February 4, 2004
DK	Notice of Opposition against European Patent No. EP 0 966 287 (European Application No. 98908091.6 entitled Oxcarbazepine Film-Coated Tablets" in the name of Generics (UK) Limited, February 9, 2004
DL	Notice of Opposition against European Patent No. EP 0 966 287 (European Application No. 98908091.6 entitled Oxcarbazepine Film-Coated Tablets" in the name of Taro Pharmaceuticals, Inc., February 6, 2004
DM	M. Gibaldi, "Biopharmaceutics and Clinical Pharmacokinetics, 4 th Edition, Lea & Febiger, Philadelphia, page 51, (1991)
DN	G.S. Banker, C.T. Rhodes, Marcel Dekker, Modern Pharmaceuticals, pp. 133, 335, 336, 3 rd Edition, New York, (1995)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO.

4-21233A

APPLICATION NO.

09/367,361

APPLICANT

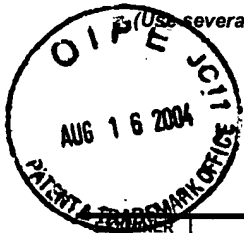
Burkhard Schlütermann

FILING DATE

AUGUST 11, 1999

Group

1615



FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	CA	IE 904685 (English Language Equivalent to EP 0 435)	12/21/96	Ireland			<input type="checkbox"/>	<input type="checkbox"/>
	CB	1 310 120	3/14/73	Great Britain			<input type="checkbox"/>	<input type="checkbox"/>
	CC						<input type="checkbox"/>	<input type="checkbox"/>
	CD						<input type="checkbox"/>	<input type="checkbox"/>
	CE						<input type="checkbox"/>	<input type="checkbox"/>
	CF						<input type="checkbox"/>	<input type="checkbox"/>
	CG						<input type="checkbox"/>	<input type="checkbox"/>
	CH						<input type="checkbox"/>	<input type="checkbox"/>
	CI						<input type="checkbox"/>	<input type="checkbox"/>
	CJ						<input type="checkbox"/>	<input type="checkbox"/>
	CK						<input type="checkbox"/>	<input type="checkbox"/>
	CL						<input type="checkbox"/>	<input type="checkbox"/>
	CM						<input type="checkbox"/>	<input type="checkbox"/>
	CN						<input type="checkbox"/>	<input type="checkbox"/>
	CO						<input type="checkbox"/>	<input type="checkbox"/>
	CP						<input type="checkbox"/>	<input type="checkbox"/>
	CQ						<input type="checkbox"/>	<input type="checkbox"/>
	CR						<input type="checkbox"/>	<input type="checkbox"/>
	CS						<input type="checkbox"/>	<input type="checkbox"/>
	CT						<input type="checkbox"/>	<input type="checkbox"/>
	CU						<input type="checkbox"/>	<input type="checkbox"/>
	CV						<input type="checkbox"/>	<input type="checkbox"/>
	CW						<input type="checkbox"/>	<input type="checkbox"/>
	CX						<input type="checkbox"/>	<input type="checkbox"/>
	CY						<input type="checkbox"/>	<input type="checkbox"/>
	CZ						<input type="checkbox"/>	<input type="checkbox"/>

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO.

4-21233A

APPLICATION NO.

09/367,361

APPLICANT

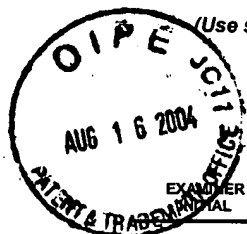
Burkhard Schlütermann

FILING DATE

AUGUST 11, 1999

Group

1615



OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

DA	Remington, "The Science and Practice of Pharmacy", 19 th Edition, pp. 1449, (1995)
DB	Extract from M-Tec website
DC	SPC for Trileptal Available from the eMC
DD	N. Kitamori, "Effect of Drug Content and Drug Particle Size on the Change in Particle Size During Tablet Compression", J. Pharm. Pharmacol. Vol. 31, pp. 505-507, (1979)
DE	S.H. Yalkowsky, S. Bolton, "Particle size and Content Uniformity", Pharmaceutical Research Vol. 7, pp. 962-966
DF	Declaration of Raj Suryanarayanan regarding EP 0 966 287
DG	Curriculum Vitae of Raj Suryanarayanan
DH	Declaration of Mohammed Safadi
DI	Curriculum Vitae of Muhammed Safadi
DJ	M. Dam et al. Euro. J. of Clin. Pharmacol, Vol. 2, pp. 59-64, (1981)
DK	M. Dam and P. Jensen, Antiepileptic Drugs, 3 rd Edition, Chapter 66, pp. 913-924, (1989)
DL	Raj Suryanarayanan, Powder Diffraction, Vol. 5, No. 3, pp. 155-159, (1990)
DM	Noyes and Whitney, JACS, Vol. 19, pp. 930-932, (1897)
DN	Translation of the relevant parts of Rudolf Voigt, Lehrbuch der pharmazeutischen Technologie, 6 th edition, pp 635-638

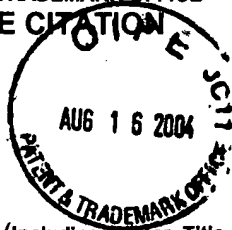
EXAMINER

DATE CONSIDERED

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)



ATTY. DOCKET NO.
4-21233A
APPLICATION NO.
09/367,361
APPLICANT
Burkhard Schlütermann
FILING DATE
AUGUST 11, 1999

Group
1615

EXAMINER
INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

DA	Trileptal Basic Drug Information issued March 24, 1993 (19 pages)
DB	English Translation of WO94/15610 (4 pages)
DC	Report B 84/1989 dated October 3, 1989 (2 pages)
DD	Clinical Pharmacology Report No. 47680 02 029, dated July 17 1998 (4 pages)
DE	
DF	
DG	
DH	
DI	
DJ	
DK	
DL	
DM	
DN	

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.